

CLAIMS

1. A method of improving reproducibility of insulin delivered by

5 inhalation, comprising:

aerosolizing a formulation comprising monomeric insulin;

inhaling the aerosolized formulation into the lung of a patient in need of insulin in a manner which allows the particles of the insulin to deposit on the lung tissue.

10 2. The method of claim 1, wherein the insulin is insulin lispro.

3. The method of claim 1, further comprising:

measuring the patient's glucose level.

15 4. The method of claim 3, further comprising:

repeating the aerosolizing, inhaling and measuring in a manner so as to maintain the patients glucose level in a desired range.

20 5. The method of claim 4, wherein each aerosolizing is carried out to create an aerosolized dose containing substantially the same amount of insulin.

6. The method of claim 5, wherein the inhaling is carried out with different inhaled volumes of air while maintaining essentially the same blood concentration versus time profile in term of affect on glucose level.

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7. A method of maintaining a diabetic patient's blood glucose level within a desired range, comprising:

administering monomeric insulin to the patient by inhalation.

30 8. The method of claim 10, wherein the monomeric insulin is insulin lispro.

9. The method of claim 7, further comprising:  
orally administering a sulfonylurea drug to the patient.

5 10. The method of claim 9, wherein the sulfonylurea drug is selected  
from the group consisting of acetohexamide, chlorpropamide, tolazamide, tolbutamide,  
glipzide and glyburide.

11. A method of enhancing the rate at which an inhaled drug migrates  
into a patient's circulatory system, comprising:

10 aerosolizing a formulation comprised of a monomeric insulin;  
inhaling the aerosolized formulation into lungs of a patient and allowing  
particles of the monomeric insulin to deposit on lung tissue.

15 12. The method of claim 11, wherein the monomeric  
insulin is insulin lispro.

13. The method of claim 11, further comprising:  
heating air surrounding the aerosolized formulation.

20 14. The method of claim 11, wherein the aerosol comprises  
particles having a diameter in the range of about 1.0 to about 4.0 microns.

15. The method of claim 11, further comprising:  
repeating the aerosolizing and inhaling a plurality of times.

25 16. The method of claim 15, wherein the formulation is aerosolized by  
being forced through a porous membrane from a disposable container.

17. The method of claim 1, wherein the formulation is a liquid formulation comprised of a pharmaceutically acceptable carrier and insulin lispro and is present in the container; and

wherein the pores have a cross-sectional configuration with a small end

5. opening of 0.25 to 6.0 microns in diameter and a large end opening of 2 to 20 times the diameter of the small end.

18. A method of aerosolized insulin delivery comprising:

10 aerosolizing a formulation comprising insulin;

inhaling the aerosol with a volume of air;

measuring the inhaled volume of air; and

15 providing a signal when the inhaled volume reaches 80% or more of lung capacity of the lungs of an inhaling patient.

19. The method of claim 18, further comprising:

repeating the aerosolizing, inhaling and measuring a plurality of times while obtaining substantially the same total inhaled volume for each delivery.

20. The method of claim 19, wherein the aerosolizing and inhaling are

20 repeatedly carried out at substantially the same inspiratory flow rate and inspiratory volume.